

USAWC STRATEGY RESEARCH PROJECT

**Striking at the U.S. Army's Strength: Soldiers.
The Imperative of Bio-Technology for Force Health Protection**

by

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ABSTRACT

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Carl Von Clausewitz wrote that a blow directed against a center of gravity has the greatest effect. Soldiers, as a powerful hub for transformation, are the Army's metaphorical center of gravity. Soldiers integrate technology, doctrine, and warfighting skills to create the centripetal force that Clausewitz described as necessary to maintain an armed forces' balance. Currently, the most lethal weapons that terrorists possess in their arsenal are biological weapons of mass destruction (WMD) because these weapons strike at the U.S. Army's biological center of gravity--its soldiers. By using bio-WMD, terrorists can achieve an effects-based calamity that, by contaminating and killing soldiers, can degrade the Army's capabilities. The current chemical-biological (CB) doctrinal framework of contamination avoidance, protection and restoration is inadequate to protect soldiers against emerging biological warfare (BW) agents. Furthermore, it does not support the Army's transformation vision of increased agility and survivability. It is imperative to research, design, then field a force health protection net for soldiers that emphasizes soldier immunity to BW attacks and can predict soldier survivability. Currently, knowledge gaps exist in technology that can quantify BW exposures, science that defines dose-related physiologic responses, and validated research that analyzes the long-term health effects of either acute or chronic exposures. These gaps prevent appropriate medical resource allocation, hinder policy development, and can lead to operational risks. Current force health protection doctrine and policy that focuses on minimizing exposure to BW agents or defining the agent then implementing appropriate controls, must broaden to include bio-technological advances in order to provide a comprehensive health protection net for deployed service members. This paper will analyze the issues, discuss potential implications, and make recommendations for bio-defense policy and doctrine development related to the use of bio-technology as a strategic enabler of force health protection.

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STRIKING AT THE U.S. ARMY'S STRENGTH: SOLDIERS. THE IMPERATIVE OF BIO-TECHNOLOGY FOR FORCE HEALTH PROTECTION

It is imperative to implement, at this critical juncture in the evolution of bio-technology and warfighting, a cohesive, focused biodefense (BD) program that defeats future biological threats and comprehensively protects military forces as well as the American people. This research paper will analyze and discuss the implications of using an operational model to redirect the United States (US) BD program. The purpose of this paper is to propose the use of an operational model for BD to guide and provide structure for the US BD program. The model, as discussed here, applies to deployed battlespaces. However, use of the model has wide-ranging implications for homeland defense, which are beyond the scope of this paper. This paper represents an examination of the framework and concepts currently driving BD policy and acquisition. The paper will analyze the current BD policy of contamination avoidance, protection and sustainment relative to the bio-threat and the Army transformation imperatives of increased soldier agility and survivability. This paper will provide recommendations to broaden current BD policy in an effort to eliminate human biology as a target for bio-weapons of mass destruction.

EXAMINING THE THREAT

Leaders at the top of al-Qaida's hierarchy...completed plans and obtained the materials required to manufacture two biological toxins-botulinum and salmonella.... The emerging picture indicates al-Qaida's biochemical weapons program is considerably more advanced than U.S. analysts knew.¹

—The Atlanta-Journal Constitution, March 23, 2003

The demise of the Union of Soviet Socialist Republics forever changed the delicate balance of competing influences--capitalism and democracy vice communism--and brought with the demise both uncertainty and new threats. The great communist menace could no longer control the various terrorist organizations, rogue states and other non-state actors (i.e., religious zealots, anarchists) and thus, the focus of our national defense organization needed to adapt to more non-asymmetric threats.

Bio-warfare (BW) has emerged as the most credible threat to our military forces as well as our civilian population, where the events of 9/11 will forever remind us that our enemies will take every measure and make every sacrifice to bring the message of hate that only these acts can fully present to our homes and in our lives. The evidence from al-Qaida training camps, and

that presented by Secretary of State Colin Powell to the United Nations' Security Council in February 2003 can lead to only one possible conclusion--the threat of BW is real and growing.

One could ask why is the threat growing when other options are equally inviting to those who challenge the US role in the world? The very inscrutability of bio-weaponry makes it an attractive weapon of choice for terrorists and rogue regimes to accomplish their goals. Bio-agents are colorless, odorless, and tasteless and cannot be seen. There are no known antidotes for most of these bio-agents. They can be disseminated efficiently with minimal risks to the perpetrator and consequences that appear as random events can easily multiply exponentially. Our adversaries see these weapons as a truly "poor man's atomic bomb" with none of the associated manufacturing and delivery issues associated with nuclear weapons. Even with our overwhelming military superiority, bio-weapons attack our most vulnerable yet basic system--the soldier.

The logical starting point for planning the defensive strategy necessary to negate the bio-weapons threat is an accurate BW threat assessment. This is not a unique approach but rather mimics how the Army identifies and counters conventional warfare threats. Michael Moodie, President of the Chemical-Biological Arms Control Institute, argues there is a pressing need for better BW threat assessments. According to Moodie, BW threat assessments currently focus on vulnerability, which can be an infinite variable, rather than risks and, as a result, provide little criteria or metrics with which to plan.² He concludes there is a tenuous link between BW threat assessments, and capacity-building for US military bio-attack mitigation strategies. US national intelligence agencies have analyzed the BW capabilities of various countries (Table 1).

Country	BW Capabilities
North Korea	Limited quantities of toxins, anthrax, cholera, plague.
China	Advanced biotechnology infrastructure; have weaponized BW agents.
India	Possesses necessary bio-technology infrastructure to produce BW agents.
Pakistan	Limited BW research and development. Continues to seek resources to expand its BW infrastructure.
Iran	Necessary bio-technology infrastructure; possibility of stocks of BW agents/weapons.
Iraq	Weaponization of anthrax, botulinum toxin, aflatoxin.
Syria	Limited bio-technology infrastructure.
Libya	May be able to produce small quantities of biological agent.
Russia	Previously world's largest BW program. Many of the program's former scientists unemployed; possess advanced knowledge of BW agents/weaponization.
Non-state (terrorists)/Al-Qaeda	Pursuing a sophisticated BW research program.

TABLE 1. BW CAPABILITIES OF VARIOUS COUNTRIES³

However, due to the commercial and military nature of bio-technology, the acquisition and development of military BW capabilities is a very dynamic and fluid threat. Rogue states of modest power but with outsized ambitions such as Iraq, North Korea and Iran see BW capabilities as not just a means to intimidate their immediate neighbors, but as an effective way to get America out of the way.⁴

Various international treaties put controls into place to limit acquisition of BW technology and capabilities does little to slow the challenge of regional BW proliferation. For example, the 1975 Biological Weapons Convention, implemented to restrict use, transfer, and development of BW and toxins has several key drawbacks with respect to declaration and enforcement. Ambassador Donald Mahley discussed the hazards of providing the extensive information required by the Convention relative to the US Bio-Defense Program, stating that such disclosure would provide "a proliferator or terrorist with a roadmap to exploit our vulnerabilities."⁵

Moodie calls for a strategic, integrated response to the BW threat that "defines the contribution of each individual tool of policy, relates them to one another, and integrates them" so that they all "work together toward the achievement of defined goals and objectives."⁶ Bio-defense research and development presents unique challenges because of the difficulty required to "distinguish between offensive and defensive research on dangerous pathogens and toxins."⁷ In January 2003, the Department of Health and Human Services and the U.S. Department of Agriculture published new safety measures that established stringent controls on selected, potentially hazardous biological agents and toxins.⁸ Recently, editors of several scientific journals censored articles they felt could compromise national security, regardless of their scientific merit.⁹ Tara O'Toole, Director of the Johns Hopkins Center for Civilian Biodefense Studies calls bioterrorism research, the "dark side of science,"¹⁰ as it represents the numerous challenges inherent in researching a multi-dimensional, complex threat such as BW. Simply genetically altering an agent could, theoretically, make it exempt from national and international regulations such as the ones discussed above.

BW represents an ill-defined, inscrutable threat that will continue to proliferate in the future. Rapid technological advances will allow nations and agencies to develop bioagents that are more difficult to detect, with more innovative delivery systems. A futures approach is needed that progresses beyond our present limited capabilities to contain and deter the growing BW threat to one that better focuses on and links bio-technology acquisition with specific threat assessments. A framework of discovery is urgently needed that can predict future requirements for bio-technology research and development and envisions future BW counterproliferation

doctrine and policy. Such a framework that looks well into the future will serve as a strategic enabler for the protection of deployed U.S. and allied military forces.

DOCTRINE

Time to time you have to jump and explore those things that are well away from the core competency. This is new competitive space, creating a new reality. This is a key element of transformation.¹¹

—Vice Admiral Arthur Cebrowski

The current DOD bio-warfare defense doctrinal framework of contamination avoidance, force protection and restoration is somewhat naive in light of emerging new threats such as mailed anthrax spores, readily available vials of toxins that can be strewn across salad bars, and environmental concerns over bio-threats to livestock and crops. Military BW defense doctrine is based on the tenet of contamination avoidance, as is the case for chemical warfare, assuming the threat would most likely come in an aerosolized form disseminated in air from a missile or aircraft. The bio-defense concepts of force protection and restoration stem from this same assumption. Force protection consists primarily of individual physical protective suits and collective shelter protection, all designed to protect the individual soldier from an aerosolized threat. Restoration or decontamination focuses on removing or neutralizing the agent from the skin, equipment and/or environmental surfaces in order to restore the functionality of the contaminated individual or unit. Medical Field Manual (FM) FM 4-02.7 describes a bio-attack as the "enemy use of bomblets, rockets, spray or aerosol dispersal, release of anthropod vectors and terrorist or insurgent contamination of food and water."¹² This definition acknowledges the wide diversity of bio-threat delivery. President Bush's proposed 2004 budget contains extensive funding for biosensor research, which underscores the focus on a "detect to avoid" contamination avoidance policy.¹³ Clearly, a new BW defense doctrinal framework is needed that is in step with the Army's transformation imperatives of increased survivability and agility and supports the new National Security Strategy's dialogue which advocates proactive, if not pre-emptive, strikes.¹⁴ This new framework will require strategic objectives that support innovative bio-technology research and development, provide improved options for diplomatic strategies and policy development, and expand legal measures and the option of early use of military force in bio-contaminated battlespaces.

CONTAMINATION AVOIDANCE: DETECT TO AVOID

Currently, threat identification and threat response depend heavily on the threat delivery means and a detector's reliability. The limited ranges of current bio-detectors coupled with their

heavy logistics load, does not allow for identification and an agile response to an unanticipated event as recent events have demonstrated that "terrorists do the unexpected."¹⁵ Major General (Retired) John S. Parker, former Commander of the Army's Medical Research and Materiel Command at Ft. Detrick, Maryland stated, with regard to mailed anthrax, "detect to avoid is not really possible."¹⁶ His point highlights the fallacy inherent in a doctrine of contamination avoidance as a framework for strategic decision-making. Transforming technology that reaches beyond bio-detectors will more closely mirror the future reality of soldiers fighting in a biologically contaminated warspace or interfacing with undetected and undetectable BW agents.

One of our greatest challenges in current developed bio-detection capabilities is the infinite number of naturally occurring and man-made biological toxin combinations. The vast array of toxins makes it difficult for bio-detectors to rapidly identify and quantify BW agents with certainty. Also, bio-detectors can only detect to avoid, i.e., after an attack has occurred. Their ability to "detect to protect," i.e., provide early warning of a bio-warfare attack, is still in development. The Department of Defense (DOD) BD research and development program, which was fairly static prior to the events of 9/11, is now urgently attempting to satisfy immediate BD equipment requirements with significantly improved BW detection and identification capabilities. Subsequently, current technology acquisition for operational maneuver focuses on funding "integrating systems that provide increased detection sensitivity, lower detection thresholds, specificity across the evolving spectrum of threat agents, and decreased false alarm rates."¹⁷ Technical limitations of currently fielded military point and standoff detection devices include limited BW agent discrimination and quantification, high rates of false positives and negative alarms, and an inability to completely eliminate ambient biological background.¹⁸ The current system also requires significant power and high levels of logistical support and is overly large.

BW agent discrimination and quantification are further hampered by lack of research and understanding of the spectral properties of the numerous arrays of BW threat agents. Problems in BW agent quantification arise from atmospheric absorption and natural background interference. Furthermore, sensor slowdowns occur as a result of their decreased sensitivity and the requirement to integrate arrays of bio-sensors with other technologies such as electronics and fluidics. Another factor hampering detector reliability and validity is the instability of biologically active molecules. Military operations may make it necessary to store detectors for long periods along a supply route where they will need to be able to withstand climactic extremes.¹⁹

PROTECTING SOLDIERS

The focus of DOD's Chemical and Biological Defense Program (CBDP) is clearly soldier protection and survival. The stated goal of the CBDP is to "provide world-class chemical and biological defense capabilities to allow the military forces of the United States to survive and successfully complete their operational missions...in environments contaminated with chemical or biological warfare agents."²⁰ Soldier survival from a BW attack is based on creating effective individual and collective protection methods.

INDIVIDUAL AND COLLECTIVE PROTECTION

Inherent to the Program's soldier survival is the principle of barrier protection for both individuals and groups, pending eventual decontamination. Protective suits such as the Joint Services Lightweight Integrated Suit Technology (JSLIST) overgarment and the Multi-purpose Overboot (MULO) are the latest developments. The suit prevents chemical exposure. The wearer's comfort and combat effectiveness requires that the suit be "lighter, less bulky and suitable for wear during all combat operations."²¹ However, no mention is made of the abilities of the suit to protect against BW agents; only that it "increases chemical protection for joint services."²²

A much needed enhancement of current collective protection design requires a significant decrease in the logistics burden and improvements in filtration, environmental controls and power generation. There is no mention of the shelter's ability to protect against a BW-contaminated individual either inadvertently or deliberately entering the shelter. DOD's protection requirements primarily focus on decreasing degradation to soldier performance and secondarily, on effective soldier protection. This assumes that the individual or collective protection is used in a timely manner, and used correctly, and that the threat agent is delivered via aerosol dispersion. Such barrier protection, i.e., donning protective suits or seeking shelters, only provides protection when adequate, timely prior detection of agents is available. So, "detect to protect" relies heavily on a first-line of bio-sensors that early warns soldiers in time for them to don their suits, and seek shelters, assuming either is readily available.

MEDICAL COUNTERMEASURES

Medical countermeasures for BW agents include vaccines and antidotes. The key challenge to development of effective vaccines is primarily the growing ability to genetically engineer bio-threats designed specifically to defeat detection and protection capabilities.²³ The vast array of bio-weaponry available, limited only by an enemy's imagination, presents an ill-defined and moving target for pharmaceutical research and development. Ultimately, the

challenge will be to keep available vaccinations, anti-virals, antibiotics and medical therapeutics well ahead of emerging virulent BW agents that have been genetically engineered to be antibiotic-resistant and overcome any fielded protective capabilities.

The most widely used countermeasure currently is pre-deployment active immunization. As vaccinations are developed to prevent specific diseases, the threat must be known or assumed in order to give the appropriate threat-specific vaccine. "Detect to protect" requires not only bio-sensors, but also adequate medical intelligence to identify potential bio-threats in order to provide the correct vaccines. Nevertheless, scientists have reported that such a potent "cocktail" of toxic substances comprised of moderate stress, the insecticide DEET, permethrin and the nerve agent antidote pyridostigmine bromide, may have been a causative agent of the infertility and sexual dysfunction found among veterans of the 1991 Gulf War.²⁴ The question then becomes not how to protect against a single, detected threat, but how best to protect soldiers against an infinite arsenal of bio-chemical mixtures, that, when combined with a soldier's own physiology, might prove toxic. Post-exposure methodologies such as improved antibiotics are in development but again, are agent-specific and rely on knowing what the soldier was exposed to as well as an in-depth knowledge of the pathotoxicity of the agent. Antibiotics are effective against bacterial agents but ineffective against viruses and toxins. Dr. Ken Alibek, formerly of the Soviet military bio-weaponry program, believes there are too many different threats for vaccine research and development to be affordable and practical.²⁵ An independent panel review of the DOD vaccine production process reported that DOD vaccine requirements cannot be accomplished singly by either DOD or the pharmaceutical industry and that available funding did not match required financing for pharmaceutical research and development.²⁶

BW AGENT DIAGNOSTIC SYSTEMS

Both protective suits and vaccines are dependent on threat notification and/or identification. Medical countermeasures, to be effective, require timely and accurate pathogen identification. The Defense Advanced Research Projects Agency (DARPA) is concentrating on developing capabilities to rapidly identify pathogens, even without the presence of soldier symptoms.²⁷ Pathogen recognition must be timely, sensitive and specific enough to tailor a soldier's medical treatment and prevent incapacitation and death. The Joint Biological Agent Identification and Diagnostic System (JBAIDS) is a portable diagnostic laboratory that will be able to simultaneously identify multiple BW agents in submitted samples.²⁸ Technical challenges to producing this technology are developing the reagents that are pathogen sensitive and specific; designing processing methods that can be used with a variety of clinical

specimens such as blood, sputum, feces and tissue; and overcoming the vast genetic variability of markers used for diagnostic development.²⁹

MEDICAL TRAINING

Finally, protecting the force from BW agents includes training for those who are responsible for treating contaminated soldiers. The Government Accounting Office (GAO) identified several medical readiness gaps in training needed for specific groups and methods to evaluate proficiency.³⁰ They also highlighted deficiencies in treating NBC casualties in a joint service environment. Army medical NBC training is focused on patient care (clinical skills), leader development (NBC casualty management), and medical force health protection (preventive medicine).³¹ Many optional courses, such as the Medical Management of Chemical and Biological Casualties Course, sponsored by the Army Medical Department Center and School, provide DOD physicians, physician's assistants and nurses with information about CB threats and medical defense strategies. Mandatory NBC training for medical personnel is notable only at the Army Medical Department's company grade and junior NCO levels.³²

At the unit level, NBC training is focused on fundamentals, such as donning protective masks, rather than on training for continuous operations in a NBC environment.³³ Joint training for physicians lacks standardized protocols for patient treatment.³⁴ The greatest drawback to training medical forces for a bio-threat is the absence of a cohesive strategy that addresses who should be trained, to what extent, when training should occur, and how best to flex training to adjust to emerging threats and technology. New methods for evaluating training are needed that not only capture proficiency, but can measure intangibles such as a medic's ability to critically think in a novel threat situation.

Transforming current bio-protection doctrine for the 21st century will require soldier protective methods that eclipse barrier protection and instead, truly protect the soldier from the threat rather than simply protecting the soldier from the environment. It will require sophisticated technology that focuses on management of BW agents at the cellular level of a soldier's physiology instead of a focus on the cellular structure of a pathogen. Finally, a framework for medical readiness training is needed that incorporates future medical NBC training requirements, implementation and evaluation strategies and methods to flex training to counter emerging threats and technologies.

SUSTAINMENT: PROJECTING THE IMPACT OF BW ON MEDICAL CAPABILITIES TO CONSERVE THE FIGHTING STRENGTH

MEDICAL PLANNING

The October 2001 GAO report on medical readiness stated the planning tools used by DOD to predict medical requirements "lacked features required to adequately plan for CB support or to assess the effect of CB warfare on the appropriate mix of medical specialties".³⁵ A DOD supplemental response recommended that medical readiness response requirements be re-evaluated in light of the asymmetric nature of the chemical, biological, radiologic, nuclear, explosive (CBRNE) threat post-September 11, 2001.³⁶ There are several models available for estimating CB casualties and bed requirements. However, all such models vary depending on key programmed assumptions that drive casualty rates. Further, most programs do not specify the medical specialty mix required.³⁷ Precise bio-warfare casualty estimation depends on a variety of factors such as the bio-agent used; troop configuration and intensity of the conflict; atmospheric conditions, evacuation rates and the availability of protective equipment.³⁸ The lack of adequate medical planning models significantly limits the potential for adequate medical response.

In May 2000, the Department of Justice sponsored an exercise called TOPOFF, using CB and radiological scenarios to "assess the nation's crisis and consequence management capacity under extraordinary stressful conditions."³⁹ The lessons learned in the aftermath of a simulated release of plague at the Denver Performing Arts Center were numerous. As the "contagion" spread, the numbers of sick people visiting emergency departments "escalated to ten times the usual caseload."⁴⁰ Hospitals quickly exceeded their capacity to care for contaminated patients along with their other actual patients needing treatment. Space ran out to triage and then treat patients. "Dead" bodies began to accumulate in the emergency departments and wards. Many "worried well" patients sought treatment because of their close proximity to the bio-release, which further blurred the parameters for rapid triage.⁴¹ Ventilators were quickly in short supply, and antibiotic supplies were exhausted early in the exercise. Security issues, particularly those regarding maintenance of isolation and containment procedures, were only notational during the exercise as "there were not enough people to manage this event."⁴²

Although medical planning tools such as Veridian Corporation's Nuclear Biological Chemical Casualty and Resource Estimation Support Tool (NBC CREST) increased medical planning capabilities by modeling specific NBC scenarios to delineate casualties and required

medical resources, the tools cannot model the infinite number of potential NBC scenarios⁴³. Subsequently, medical planning models are urgently needed that can approximate numbers of BW casualties, in any scenario, then predict the medical resources required to treat and sustain BW-contaminated casualties and manage contaminated fatalities. Specifically, models are needed to provide information on specific types of complex medical equipment and supplies needed, such as ventilators and monitoring capabilities. A sophisticated model that delineates the medical specialty mixes required for a BW attack (i.e., physicians, nurses, medics) can also help determine other personnel requirements such as security and NBC-qualified individuals. Models that predict casualties can help with hospital design to insure adequate space for triage and immediate treatment. Computational modeling can maximize medical resources and minimize casualties thereby improving medical readiness and response.

SOLDIER HEALTH EFFECTS

Currently, there is no adequate methodology to predict short or track long-term soldier health effects from exposure to a BW agent. The prevailing logic of individual protection is that unprotected soldiers exposed to a BW agent will either survive the attack, depending on many variables such as threshold of exposure and the soldier's immune system, or develop symptoms associated with the BW agent and then be medically treated accordingly. Nevertheless, there is little epidemiological information that details the long-term occupational health of victims contaminated in a BW attack. Historical data provides examples of bio-attacks, but the information is mostly anecdotal (Table 2).

1940	Bubonic plague epidemic in China and Manchuria following overflights by Japanese aircraft that dropped infected fleas together with grain, which attracted the local rat population.
1975-1983	Laos and Kampuchea attacked by aircraft delivering colored aerosols ("Yellow Rain"). Afterwards, humans and livestock became ill and a low percentage of those stricken died.
1979	Sverdlovsk (now Yekaterinburg), in the Soviet Union, experienced a loud explosion later determined to be originating from Military Compound 19. Residents downwind of the compound experienced high fevers and difficulty breathing. The final death toll was estimated between 200 and 1,000. In the summer of 1992, President Boris Yeltsin reported that the incident was an accident involving the escape of aerosolized anthrax spores from the military research facility.
1984	Two followers of the Rajneesh Bagwhan produced then dispensed Salmonella bacteria in the salad bars of local restaurants in order to affect the outcome of a local election.

TABLE 2. HISTORICAL OVERVIEW OF BIO-ATTACKS⁴⁴

Soldier baseline health data coupled with exposure data and the data accumulated from short or long-term bio-monitoring is required to help build roadmaps to predict health effects post-BW agent exposure. Once the health effects are known, then the medical community can

design proactive measure to prevent the potential acute and chronic outcomes of an exposure to a BW agent.

There is no method, currently, for predicting morbidity and mortality of soldiers attacked with a BW agent other than onset and severity of symptomatology. In the future, soldiers may be exposed to genetically engineered bacterial pathogens that are antibiotic-resistant and resistant to environmental degradation. They can be exposed to immunologically-altered viruses that are not only resistant to vaccines but can easily slip through bio-detection devices. Covert BW agent releases may be the poor man's "smart bombs" of the future because they strike quietly and efficiently at a soldier's weakest point---his or her own physiology. This makes BW agents quite effective because with many agents, such as inhaled anthrax, by the time the symptoms are detected; the exposure is fatal, regardless of treatment. With exposure to contagious BW agents such as the smallpox virus, exposed soldiers, unlike a chemically contaminated soldier, can unknowingly exponentially expand the scope of the attack.

The CBDP is developing research aimed at understanding soldiers' gene expression patterns and how these patterns change after exposure to BW agents. This research can provide biological markers that will support early detection of exposure to BW agents thereby facilitating rapid medical treatment.⁴⁵ However, the very complexity of each soldiers' physiology makes the task of designing and implementing such epidemiological studies particularly daunting. For example, at a known threshold of exposure to most BW agents, all soldiers exposed will become ill. The predictability of casualties associated with lower thresholds of exposure and chronic BW agent exposure is unknown. Current issues that deter adequate health surveillance are: inability to track time and location of soldiers while deployed in order to link location with potential for exposure, no adequate baseline soldier health database, and no methodology for bio-monitoring post-exposure.

A FRAMEWORK FOR DISCOVERY: SENSE, SHAPE, SHIELD, SUSTAIN

The Institute for Defense Analysis (IDA), in 2002, developed a framework for "An Operational Concept for Biological Defense."⁴⁶ The four elements of the operational concept were defined as:

- Sense - situational awareness
- Shape - shape the battlefield
- Shield - soldier protection
- Sustain - maintain, restore military operations

Although joint planning language is integrating these terms, actual NBC capabilities have yet to catch up. For example, "sense and shape" reflects current acquisition of networked bio-

sensors arrayed across the battlefield to avoid BW contamination. "Shield" defines soldier protection as barrier protection, and "sustain", as previously discussed, means decontaminate to restore soldier and unit capabilities. This operational conceptual model must expand to become broad enough to propagate new strategic concepts rather than just embracing old operational guidelines. "Sense" must expand to include not only sensing the environment to detect BW agents, but individual soldier sensing and medical surveillance, both at the soldier's physical level and physiologic level. "Shape" must include more than transforming the battlefield. "Shaping" the threat is already on the horizon as scientists are finding new ways to neutralize BW toxins. The concept of shielding the force must allow for extensive forays into bio-technology research and development to improve shielding methods beyond barrier protection that insure soldiers are immune to the threat of BW. The model must include avenues for expansive exploration of the products of small bio-technology firms developing dual-use technology that promotes soldier agility and lethality in future conflicts. Finally, "sustaining" must encompass more than the concept of maintaining military operations. It must expand to become a more proactive concept of promoting military operations via tools such as mathematical modeling and information management capabilities that proactively project and identify requirements.

SENSING AS THE NEW DETECTIVE

The term "sense" defined as "an ability to judge, discriminate, or estimate external conditions"⁴⁷ is notably different from the definition of "detect" as "to discover something hidden."⁴⁸ The current concept employing bio-detectors to grossly sample the environment, as defined by a perimeter of deployed sensors, focuses on the atmospheric environment rather than the soldier as the environment. Arraying a networked bio-detector system around a force limits that force's agility and lethality by the unwieldy footprint of the system, no matter how mobile. Such a system could not adequately protect a rapidly moving special operations unit whose very value depends on their stealth and speed. As the majority of the medical CB countermeasures focus on the individual (vaccines, etc.), so also should sensing systems be individual-based.

Micro-electromechanical system (MEMS) research is producing "Smart Dust," a self-organizing network of wireless ultra-tiny computers and communications devices that determine, autonomously, how best to collect data, collect it, and then perform required operations.⁴⁹ Potentially, these networks can surround and move with individual soldiers. Then, upon sensing a BW direct inhaled or ingested threat, Smart Dust networks internal to the soldier can deliver

the required prophylaxis into the soldier's bloodstream or activate an enhanced response from the soldier's immune system.

One of the limitations of current detection systems is their inability to detect covert BW agent releases from anything other than an aerosolized release into either the physical environment or in a building. The systems are not finely-modulated enough to sense an infected person deliberately spreading infectious disease and, with such a scenario, predict and/or track the path of contamination. Dispersion modeling research coupled with mathematical modeling of the progression of various BW agent diseases such as anthrax, holds promise for not only predicting the dispersion of a BW agent attack, particularly in urban environments, but also predicting survivability of the individual. For example, Dr. Shahrouz Aliabadi is working with DOD high performance computers to build exquisitely detailed, high-speed dispersion models for CB releases in urban areas.⁵⁰ Dr. Yoram Vodovotz, at the University of Pittsburgh, has developed a mathematical model that incorporates the physiological details of an acute inflammatory response to infection. He and his group report that they can simulate the inflammatory response to an anthrax infection.⁵¹ Such a model can predict an individual's response to a disease and consequently predict their survivability.

Mathematical modeling of a BW-acquired disease, when coupled with agent dispersion modeling that pinpoints a soldier's location as a junction defined in the dispersion model, can not only predict the patient's course of disease, but can improve patient triage for medical treatment. It can also define the pool of individual's requiring medical intervention and help tailor each soldier's medical treatment regimen.

Another important research and development area that promises advances in bio-sensing is physiological biomarkers of environmental exposure. Biomarkers are those "biochemical, physiological, morphological, and histopathological responses or organisms that signify exposure to contaminants."⁵² Biomarkers can be measured in human fluids, tissues or cells. For example, Dr. Vodovotz, in his mathematical modeling of anthrax, used biomarkers associated with an acute inflammatory response to model progression of the disease. On missions where stealth and mobility preclude the use of complex sensor arrays, a soldier's blood could be sampled pre and post-mission, then analyzed for changes in inflammatory biomarkers. Combining this information with a personal global positioning technology could help pinpoint the source and nature of the BW threat. This human responder concept could provide an earlier and definitive warning of a soldier's exposure to a BW agent.

Analyzing the complex mixtures of naturally occurring biological and chemical toxins and man-made BW agents that a soldier is potentially exposed to on deployments can be a daunting

task. However, applying the concept of biomarkers and monitoring exposure to complex mixtures can greatly aid understanding of exposure consequences and identification of active components. Although the number of environmental exposures can be infinite on deployments, the number of physiological responses and soldier health outcomes is finite. By working backward from the physiologic response to the exposure, it may be possible to identify key specific biological markers or changes that can be monitored and possibly predict outcomes.⁵³

One of the essential pre-conditions to providing effective early detection of disease outbreaks is medical surveillance. A military health surveillance network called Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) tracks medical cases at worldwide military treatment facilities to determine if outbreaks of disease are occurring.⁵⁴ Similarly, a technology model called BioSentinel tracks and analyzes sales of over-the-counter medications at major pharmacy, grocer chains, and other discounters to detect anything from flu outbreaks up to a potential bio-terrorist attack.⁵⁵ Technology such as this can be used to build a joint networked medical surveillance tool that integrates data from Disease Non-Battle Injury (DNBI) reports and other operational sources to warn of significant disease outbreaks that might signal a BW attack.

To augment such a system, health care providers must be well trained and vigilant to identify early symptomatology associated with exposure to BW agents. Various medical and nursing education institutions are incorporating information on environmental issues into their curriculum. For example, the Agency for Toxic Substances and Disease Registry (ATSDR) has implemented an Environmental Health Nursing Initiative that provides training on skills such as how to take an exposure history in an effort to raise awareness about environmental health issues and how nurses can address the issues through practice, education, and research.⁵⁶ Similarly, the National Environmental Education and Training Foundation launched a plan to integrate pesticides issues into primary healthcare education and practice. These initiatives can serve as a model for integrating other environmental health issues into medical and nursing education.⁵⁷ Both models template mandatory military medical training focusing on early recognition of the symptomatology of potential BW agent exposure.

The new BW defense language that defines “sense” as detecting the environment for situational awareness must expand to include other conceptual definitions of medical “sensing” that encourage a future vision to combat emerging BW threats. Sensing must include innovative tools that sense a soldier’s biology, promote survivability and increase soldier agility. Medical training that allows health care providers to recognize the physiological responses of soldiers contaminated from BW agents can also promote soldier survivability. Also,

computational models that “sense” dispersion flow patterns of BW agents can predict and improve soldier protection and survivability.

SHAPING THE THREAT VERSUS SHAPING THE BATTLESPACE

The BW operational concept, “shape” must also include the concept of shaping the threat. Building a “threat envelope” that describes plausible alternatives and identified “hedging contingencies,” i.e., those events that no matter how unlikely, will result in enormous consequences and so require preparation, provides policy makers more realistic measures for making decisions regarding resource allocations and policy priorities.⁵⁸ Also, the threat envelope must obviate outdated assumptions. For example, a fundamental assumption for designing technology was that the operators of the technology would not do anything to jeopardize their own existence. That assumption is no longer true.⁵⁹

Shaping the BW threat must begin with international policy that seeks to prevent the proliferation of the threat. International bans on the development, transfer and possession of bio-weapons and related technology such as those enacted in the 1972 Biological and Toxin Weapons Convention, need to be strengthened to include mechanisms for monitoring and enforcing the ban. Punishment for violating the ban needs to be delineated and should include prosecution in international courts and extradition. International laws that dictate oversight of laboratories conducting research involving biological pathogens are required that are enforceable and able to be monitored.⁶⁰

Shaping the threat with national policy must result in a streamlining of DOD agencies involved in management of the Chemical-Biological Defense Program (CBDP). The Under Secretary of Defense, in a reply to the Secretary of the Army's request to integrate the DOD CBDP to make it “able to quickly respond to warfighter and national security needs and streamlined with authority and accountability vested in specific individuals,”⁶¹ directed initiatives that further fragmented the program and generated new agencies. Three agencies were charged with different aspects of the CBDP. A new office, the Joint Program Executive Office (JPEO), was established, and a new entity, the Overarching Integrated Product Team (OIPT), was implemented to “assist the Assistant Secretary of Defense (NBC) in his oversight role”.⁶² The duplicative nature of DOD programs, in this case the CBDP, must be eliminated to minimize wasteful redundancies, mis-communications and competition for resources that can slow or mis-direct policy development and bio-technology acquisition, all of which can significantly dilute any response to designing solutions for the BW threat.

International and national policy that defines controls over biological pathogens themselves must include direct language that closes loopholes allowing development of genetically engineered pathogens that can skirt requirements designed for a list of specific pathogens. The policy must be expandable enough to accommodate scientific discoveries and new technologies. Dr. Alibek's testimony to the House International Relations Committee described examples of the sophistication of the Soviet/Russia Biological Weapons Program. He concluded his testimony by stating that a new assessment of the biological capabilities of the former Soviet republics was "long overdue."⁶³ Testimony such as his should be the driving force behind international law that restricts or re-directs the proliferation of BW expertise from the former Soviet biological weapons program and from countries with growing bio-technology infrastructures.

Shaping the threat must also address future bio-threats in non-traditional battlespaces such as urban areas. The "same organizational, doctrinal and technical tools that apply to Effects-Based operations (must be) brought to bear on the urban environment."⁶⁴ Different military components with disparate skills must overlap and build redundant capabilities in order to shape the BW threat in urban warfare. For example, combining specialized elements from chemical and medical TOE companies who would train and fight together would fill a vital battlefield BW support need. The revitalized medical company would "allow us to treat military medicine as a front line force and not some support thing."⁶⁵

Shaping the threat goes well beyond shaping the battlefield to respond to a BW threat. Shaping national policy and international laws to prevent development of new and exotic BW agents can decrease proliferation of the threat. Shaping DOD agencies responsible for BW threat reduction to make them smaller and less redundant will provide a more efficient integrated approach to the threat. Shaping joint BD doctrine to provide guidelines for BD operations in future battlespaces to include the continental U.S. and urban areas will promote soldier capabilities.

SOLDIER BIO-SHIELDING VERSUS SOLDIER BARRIER PROTECTION

Research and development strategies must provide overlapping and complimentary levels of soldier protection against BW agents. A skilled microbiologist can engineer a threat that may breach vaccines or barrier defenses. As such, providing "bio-shielding" capabilities at a soldier's cellular level would provide an essential additional level of soldier protection.

Several BW agents such as anthrax, tularemia, and plague can survive intracellularly where they are relatively resistant to antibiotics.⁶⁶ In order to molecularly define these invaders,

Dr. Emilio Garcia is leading a group of researchers who are attempting to identify the specific signature of the pathogen by identifying the gene expression of the infecting bacterium. His study using *Yersinia pestis* (plague) to infect cells shows a pattern of gene expression that is quite different from that of other infections.⁶⁷ Dr. Garcia's work appears to suggest a groundbreaking early warning methodology that would signal a soldier's exposure to a BW attack.

In other studies, researchers are using large-scale cDNA microarray analysis to characterize host cell response to the intracellular infection by tularemia and plague. By studying these mechanisms, the researchers hope to be able to identify therapeutic targets.⁶⁸

Immunomodulation strategies that enhance a soldier's immune system are also showing promise for bio-error defense. Dr. Arthur Krieg postulates that the use of synthetic CpG DNA molecules, found in bacterial DNA but not vertebrate DNA, could activate innate immune defenses that protect rodents against viral, bacterial and parasitic pathogens. By pre-treating the mice two days prior to a *Brucella* challenge of the rodent's immune system, Dr. Krieg found that the treatment considerably enhanced the rodent's ability to fight and survive the disease.⁶⁹ In another investigation of immunomodulation strategies, Dr. Dennis Klinman, found that CpG ODN, not only enhanced an animal's immune system, but also increased the protective efficacy of co-administered vaccines.⁷⁰ Research such as this holds promise for new bio-shielding strategies that modulate a soldier's immune system in order to protect them against BW threats. Boosting nonspecific cellular immunity can prove to be an effective strategy to ward off BW attacks that are non-viral in nature. Relying on vaccines and antibiotics severely limits success to a small window of opportunity for effective medical treatment in the case of anthrax, plague and tularemia. Untreatable diseases such as smallpox or ebola as well as BW agents engineered to increase their resistance to drugs further limit this approach.⁷¹ As such, enhancing the immune response is an attractive dual-use strategy to either supplement or replace drugs used to attack pathogens.

Attacking the biological invaders at the molecular level can provide another bio-shield for soldier protection. Dr. James Marks found in his research that a combination of two to three oligoclonal antibodies caused extremely potent neutralization of the Botulinum neurotoxin *in vivo*.⁷² In another study, Dr. David Kranz produced soluble forms of engineered cell surface receptors that acted as potent inhibitors of enterotoxins.⁷³ Future research such as this can help better engineer improved antagonists for BW toxins. Furthermore, more research is required to identify synthetic substances that can recognize and scavenge toxins immediately after they enter the soldier's system.

“Shielding” to eclipse barrier protection will promote innovative bio-shield strategies that increase soldier protection from BW agents. Strategies that rapidly identify specific toxins at the physiological level can promote improved methods to kill the toxins. Immunomodulation therapies that confront and counter toxins in a soldier’s bloodstream and prevent disease development can effectively immunize soldiers from toxin exposure. Bio-scavengers that intercept and kill toxins in the blood stream will prevent the development of toxin-induced disease. In the future, BW researchers must aggressively work to manipulate biology in order to protect soldiers. It is that very biology that is a soldier’s Achilles’ heel.

SUSTAINING UNIT CAPABILITIES: PROMOTING VERSUS MAINTAINING

In current NBC defense doctrinal language, "sustaining" operations assumes that a BW attack will disrupt, slow, or stop unit operations due to donning protective suits, waiting for the aerosol cloud to disperse, and then decontaminating or "restoring" individual and unit capabilities. The bio-science and technology discussed previously, when fully realized and implemented, will make this assumption obsolete. As a result, sustainment should be re-defined as any concept that promotes unit and individual operations in a BW contaminated environment and will leverage technology in order to better support Army transformation concepts. Decontaminating individuals and equipment takes enormous amounts of time and significantly slows operations. Funding technology to eliminate decontamination requirements seems to be a better approach than funding development of better decontamination solvents. The technology should be as simple as the technology behind lint removers that use sticky tape to remove lint. Similar sticky strips could be impregnated with engineered threat-specific and multi-valent antigens and, when placed on humans and equipment, would collect and dissolve BW pathogens, after which they could be peeled off and discarded.

The same principle holds true with the time delays caused by soldiers donning protective suits, mask and overboots then having to remove them after the threat has cleared. Technology such as pre-exposure pills and/or treatments that confer continuous BW threat protection for soldiers can eliminate time delays and promote soldier agility. Furthermore, the concept of post-exposure prophylaxis will not easily support dispersed forces in the non-contiguous battlespace. For these soldiers, access to medical care for prophylaxis for BW exposure is not always readily available and a minimal exposure-to-treatment time is essential when treating BW agent exposure. Soldier personal networked systems that sense and identify BW pathogens then activate internal-to-the-soldier medication pumps that dispense the appropriate BW pathogen prophylaxis, will promote soldier agility and survivability.

Moving medical care as far forward as possible will also support soldiers' agility and survivability. Instead of vesting medical care with one individual, (i.e., a physician, nurse, or medic), selected aspects of medical care must move far forward with the soldier. Combining information technology with bio-technology can promote innovative, networked soldier medical care systems that are easily sustainable and rapidly restore soldier capabilities after a BW attack. Medical care that promotes, rather than just maintains individual capabilities in a BW environment will require creative concepts that, rather than re-design the medical system that supports the soldier, re-design the soldier.

Sustaining technology that eliminates decontamination requirements for soldiers and equipment can maximize soldier capabilities. Medically sustaining the soldier in a BW environment with the use of information and bio-technology that is intrinsic to the soldier better promotes soldier survivability.

CONCLUSIONS

Only by making the effort to remain at the cutting edge of science and technology advances across all fields can the Army understand what is currently possible and what the near future may hold in terms of (bio) weapons that can threaten U.S. national security.⁷⁴

—Kip P. Nygren

Mr. Bill Patrick, a bio-weaponeer with the former U.S. bio-weaponry program, stated that, with the demise of the program, the U.S. lost a capability to counter emerging threats because "we quit studying and researching new threats."⁷⁵ Also, sophisticated equipment and knowledgeable scientists are not always necessary to manufacture bio-weapons when they can be stolen from minimally secured bio-defense laboratories. For example, allegations arose that the perpetrator of the 2001 anthrax mailings acquired the spores from Ft. Detrick due to the minimal screening required by visitors to the institute.⁷⁶ The National Intelligence Council predicts that the risk that BW will proliferate is increasing.⁷⁷ Already, emerging bio-threats and asymmetric threat delivery systems are making obsolete the protection that barrier suits and vaccines are currently affording soldiers. Following are recommendations, based on a "re-visioning" of the IDA's operational concept for biological defense, for senior military leadership to consider for implementation:

- Telescope bio-sensing capabilities down from the battlespace into the soldier. The unpredictability and dynamic, fluid nature of future battlespaces prohibits the use of sensors that require early deployment, monitoring, and validation.
- Acquire immunomodulation strategies that improve human performance against BW threats.
- Integrate expanded CB training at all levels, across all services.
- Integrate mandatory training on medical management of CB casualties at all levels of the AMEDD.
- Build bio-dispersion models that integrate biomarkers of inflammation and medical surveillance data in order to quickly identify potential casualties, then provide the appropriate level of treatment based on biomarker levels.
- Blend concepts-based approaches to BD problem-solving into the functionality-based approach dictated by BD agencies currently, i.e. research and development, requirements, and procurement, to prevent stove-piping and redundancy. Assemble multidisciplinary groups composed of molecular biologists, nanotechnologists, engineers, information technologists, and physicians to identify future threats, and then build solutions.
- Design computer models capable of providing predictive bio-threat assessments based on evolving science and bio-technology, not just intelligence information.
- Eliminate decontamination as a step in the sustainment process. Develop protective systems that are internal, rather than external to the soldier.

IMPLICATIONS FOR THE FUTURE

As Saddam Hussein and Slobodan Milosevic discovered, a conventional war against the United States is a losing proposition.⁷⁸ Bio-weaponry is an attractive alternative for rogue dictators due to its high casualty yield and the significant fear that BW creates. "Terrorists count on the threat of demoralizing blows to instill massive fear and rally shadowy constituencies to their side."⁷⁹ The current tenets of WMD contamination avoidance, protection and restoration must change to counter new emerging BW threats.

Solving today's problems with today's solutions is not the preferred approach for tackling the future BW threat. The BD operational model of "sense, shape, shield, sustain" easily supports the transforming Army, provides direction for bio-technology acquisition and funding, enhances and guides policy development, and builds a framework of discovery for BD research and science. We must create a new reality that eclipses current solutions for the BW threat, and stays several steps ahead of day-to-day operational solutions in order to provide answers to questions that are yet unasked and unimagined. Leap-ahead technology must not be the sole province of the warfighter, but rather we need to be prepared to engage the asymmetric threats posed by BW wherever they emerge.

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